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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/246,307	02/08/1999	ALAN P. KOZIKOWSKI	9928-0009-99	6016

7590 06/02/2005

SCULLY, SCOTT, MURPHY & PRESSER  
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GARDEN CITY,, NY 11530

EXAMINER

GUPTA, ANISH

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 06/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/246,307

Applicant(s)

KOZIKOWSKI ET AL.

Examiner

Anish Gupta

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 January 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 12-17, 21-28, 31, 32 and 73-81 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 23-28, 31, 32 and 78-81 is/are allowed.
- 6) ☒ Claim(s) 12-17, 21, 22 and 73-77 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

S.O.O.

### DETAILED ACTION

1. Applicants request for revival has been received and the application has been revived. The last outstanding amendment was filed 7-11-01, where claim 12 was amended. Claims 12-17, 21-28, 31-32, 73-81 are pending in this application.

#### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 12-17, 21-22, 73-77 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods for enhancing cognitive function, does not reasonably provide enablement for all other types of neuroprotection in any disorder. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use, the invention commensurate in scope with these claims.

For the 112 First paragraph rejection, Applicants have argued they are not required to support their presumptively enabled disclosure. The specification sets forth variety of in-vitro tests that demonstrate neuroprotection against both acute and chronic neurodegenerative disorders. Applicants make reference to a declaration submitted by Dr. Faden in the parent application 09/022,184 that show that the compounds offered neuroprotection from excitotoxic injury, ischemic injury, traumatic injury, neurotoxic injury and apoptotic cell death caused by staurosporine. Further, the declaration filed on July 9, 2001, indicate that the compounds of the invention provide neuroprotection against chronic neurodegenerative disorders. The reliance on the Patel reference is misplaced since number of drugs have been approved prior to priority date of the invention that show reproducible cognition enhancement in patients with alzheimer's disease.

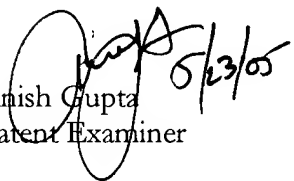
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Applicants arguments filed have been fully considered but have not been found persuasive. First, Applicants arguments and rebuttal have been limited to “cognition enhancement.” However, the claims recite “neuroprotection to a subject.” Neuroprotection is not limited to just “cognition enhancement,” but is all encompassing, including protection against cell death. The specification and the declaration have not enabled the claimed invention to allow one of ordinary skill in the art to use the claimed compounds against all types of neurological conditions that require neuroprotection. It is well known in the art that for neuronal cell death is irreversible. For example, Martin et al. states transient cerebral ischemia produces an irreversible neuronal death that is still not fully understood (see page 287 of Martin). Mattson et al. states that drugs can temporarily provide improvement in memory, but there are not treatments that can stop or reverse the inexorable neurodegenerative process in Alzheimer’s disease (see abstract of Mattson et al.). Even those references cited by Applicants state “At the present time there is no effective pharmacological therapy available which can either cure Alzheimer’s disease or stop the progression.” Furthermore, the hallmark of the Alzheimer’s disease is amyloid deposition. The specification does not reasonably provide any guidance that the compounds can effectively provide “neuroprotection” against amyloid deposition in either decreasing the progression or stopping them all together. Hsiao et al. disclose that amyloid deposition, even where therapy results in cognition enhancement, does not result in amelioration of amyloid deposition (see page 102). The Declarations submitted do not provide any insight to any of these neuroprotection and thus, one cannot readily conclude that compounds of the claimed invention provide “neuroprotection” in the cure of Alzheimer’s, reversing neuronal cell death, stopping or reversing the neurodegenerative process in Alzheimer’s disease, or protecting against amyloid deposition in the brain.

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2. Claims 23-28, 31-32, and 78-81 are allowed.
3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (571)272-0965. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can normally be reached on (571) 272-0974. The fax phone number of this group is (571)-273-8300.

Anish Gupta  
Patent Examiner

 5/23/05